






Study Protocol

Effects of Dog-Assisted Therapy on the Physical Function and Communication Skills of Adults with Autism: A Study Protocol for a Controlled Study

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Abstract: Background and Objectives: Despite the scientific evidence of the positive effects of animal-assisted therapy (AAT) in adults with autism spectrum disorder (ASD), it is not still considered an evidence-based practice for this population. The proposed study will aim to evaluate the effects of a dog-assisted therapy program on gait, posture, and communication skills. Materials and Methods: A total of 24 adults with ASD will participate in this non-randomized controlled trial. The experimental group will involve 12 participants who will receive AAT for 10 weeks, at two sessions per week. The focus of these sessions will be conducting different activities and physical exercises, facilitated by dogs. The control group will receive treatment as usual. The outcome measures will be the ability to walk and climbing stairs, balance, risk of falls and communication skills. Conclusions: The role of dogs as facilitators of the movement may lead to relevant benefits in the gait, posture and communication skills of adults with ASD, improving their ability to perform activities of daily living.

Keywords: animal-assisted therapy; autism spectrum disorder; dog-assisted therapy; rehabilitation



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1. Introduction

Autism spectrum disorder (ASD) is a range of alterations of neurobiological origin that compromises typical human development. Patients with ASD are commonly characterized, according to the DSM-5 [1], by permanent deficits in communication and social interaction, repetitive and restricted patterns of behavior, activities, and interests, which interfere in their daily functioning [2]. Although the most studied ASD impairments are social and cognitive deficits, different alterations to gait, which is an essential part of carrying out the activities of daily living (ADLs), have recently been identified, as compared with control groups without ASD [3,4]. Concurrently, reductions in cadence, stride width, gait cycle length, and in the capacity to attenuate the oscillations from the trunk to the head have been observed, in contrast with healthy controls [3,4].

Regarding therapeutic approaches, behavioral and individualized psychosocial treatments are the most frequent interventions due to the strong empirical evidence of their efficacy [5]. Although the effects of drugs are limited, they can be employed as an adjunct to non-pharmacological therapies. Currently, some evidence-based non-pharmacological practices to treat ASD symptoms are background-based interventions (ABI), augmentative and alternative communication (AAC), cognitive-behavioral strategies, differential reinforcement of alternative, incompatible or other behavior, and functional behavior evaluation, among others [6,7].

Moreover, a new therapy, animal-assisted therapy (AAT), is recently gaining popularity for people with ASD because it increases patients' physical involvement through physical or psychosocial tasks with dogs, horses, dolphins, etc. [7]. AAT, a type of animal-assisted intervention (AAI), is a goal-oriented, planned, and structured therapeutic intervention, directed by qualified professionals, and focused on the development of physical functioning and cognitive, behavioral, and/or socio-emotional patients' [8,9]. The scientific literature supporting AAT points out that this interaction with an animal could benefit users, leading to calming effects, reductions of loneliness and depression, increases in socializing and motivational effects [10]. AAT has been widely developed with ASD patients, demonstrating increases in social interaction and communication, together with reductions in behavior problems, stress, and the severity of ASD side-effects [11]. A recent study found improvements in patients' anxiety and self-esteem and showed that participants in AAT programs find it applicable and relevant because the positive results obtained by way of relaxation, fun, or self-knowledge, and the dog-contact experience itself [12]. One remarkable aspect of AAT is the positive valuation by health personnel [13,14] and the high rates of adherence, which could be related to patients' positive perception of such experiences [15].

In order to explore the previous studies conducted in the field of ASD and dog-assisted therapy, a literature review was performed. It was conducted on the well-known database PubMed. The search string used was: "(Autism) AND (dog or canine)". A total of 130 articles were retrieved on October 10, 2021 (date of the search). Of the 130 articles, 12 were concerned on the effect of dog-assisted therapies in people with ASD, focusing on social [15–18], behavioral aspects [19–24] or physiological variables, such as cortisol levels [25,26]. These articles were published between 2010 and 2021. Furthermore, 9 of the 13 articles were focused on children with ASD, which agrees with the conclusions of a previous systematic review [27]. As noted in that literature review, no prior studies have examined the effects of a dog-assisted therapy program on the main outcome measures of walking performance, balance or the risk of falling. This would be relevant due to the impact of ASD on adults physical function [3,4]. Furthermore, it would also be interesting to assess communication skills. Thus, the main aim of the current study is to evaluate the effects of a dog-assisted therapy program on the physical function and communication skills of adults with ASD. The specific objectives are to analyze the effects of AAT in patients' gait, ability to go up and downstairs, balance, communicative intention and social interaction.

Given the mentioned potential benefits of AAT in people with ASD, it is expected that the presented program would lead to improvements in physical functionality and to a consequent reduction in the risk of falls in adults with ASD. Similarly, it has been hypothesized that this program will be able to improve the communication skills and social interactions of this group.

2. Materials and Methods

2.1. Study Design

The proposed study is a non-randomized controlled clinical trial, which will be carried out in parallel in two different centers (the non-randomization design reasons are explained below). Each location will involve 12 patients, with 6 belonging to a control group and 6 to the experimental group. Therefore, the total sample will be 24 adults with ASD (12 in

the control group and 12 in the experimental group). The study methods described below follow the SPIRIT 2013 Statements Items to correctly fulfill the standard protocol items for Critical Trials [28]. As for having a clear comprehension of the design, in Table 1 represents the schedule regarding the SPIRIT guidelines.

Table 1. Study schedule following SPIRIT guideline.

TIMEPOINT	STUDY PERIOD						
	Enrolment	Allocation	Post-Allocation				Close-Out
	$-t_1$	0	t_1	t_2	t_3	t_4	t_x
ENROLMENT:							
Eligibility screen	X						
Informed consent	X						
Blinding and confidentiality	X						
Allocation		X					
INTERVENTIONS:							
Animal Assisted Therapy Group			◀────────────────▶				
Control Group			◀────────────────▶				
ASSESSMENTS:							
Sociodemographic variables	X						
Walking performance, balance and risk of falls, and ability to climb and descend stairs	X						X
Communication skills	X			X		X	
Analysis of results	X						X
Result comparison							X

t_1 : 1st–4th week; t_2 : 5th week; t_3 : 6th–10th week; t_4 : 11th week.

2.2. Ethical Approval and Registration

The study has been approved by the ethical committee of the Rey Juan Carlos University (approval number: 1901202103121) and the University of Extremadura (register identification number: 42//2021). After the positive response of the ethics committees, the trial was registered at ClinicalTrials.gov, recognized by the World Health Organization (WHO) and the International Committee of Medical Journal Editors (ICMJE), under the identification number of NCT04859998. Both the study registration and the positive ethics committee approval were obtained recruitment, whereas the current protocol was written after this process had completed.

Regarding consistency in the informed consent process, all participants or their legal guardians will be informed about all the relevant aspects of this study before starting their program. Accordingly, all will sign the informed consent before being included in the study.

2.3. Participants

A total of 24 adults with ASD will participate in the current study belonging twelve to the intervention group ($n = 12$) and twelve to the control group ($n = 12$). The study will be conducted in the center and facilities where they are usually living. The inclusion and exclusion criteria to which they were subjected are mentioned in Table 2.

Table 2. Participants' inclusion and exclusion criteria.

Inclusion Criteria	Exclusion Criteria
Enough functional capacity to walk independently	Under medical condition that contraindicates the proximity or contact with animals (exclusion criteria for the intervention group)
ASD diagnosis	Animal or dog allergy (exclusion criteria for the intervention group)
Older than 40 years old	Dog phobia (exclusion criteria for the intervention group)
Being able to go up and down stairs autonomously	History of animal aggression (exclusion criteria for the intervention group)
	Not sign the informed consent.

2.3.1. Recruitment

The initial recruitment, screening, and baseline assessment of volunteered participants will be conducted in the two Autism federated entities of Madrid (Spain), APNA (Asociación de Padres de Niños con Autismo) and Nuevo Horizonte. The study interventions will end before 2022. The entities will offer participants to enroll in the study by explaining to patients and their legal guardians the intervention requirements. Once they express their interest, more detailed written information will be proportionated together with the informed consent which they will need to sign to finally participate.

2.3.2. Randomization, Blinding and Confidentiality

As has been mentioned before, the proposed study is a non-randomized controlled trial. Thus, there will be no randomization process. The allocation of the participants will be according to the criteria of the caregivers and professionals working in the associations, based on the eligibility criteria mentioned above according to the expected response to the activity in terms of applicability, tolerance, and treatment of the dog. Although participants will know their group assignment, the evaluators from the research will be blinded. Thus, each participant will be assigned an anonymous code, so that the evaluators will not know the allocation of patients. Moreover, personal information will be stored only for clinical research purposes and will be password protected to maintain confidentiality.

2.3.3. Sample Size

The sample size was calculated using G-Power 3.1 and based on data from Garcia-Villamizar, et al. [29]. They achieved a significant improvement in the two subscales of the Tinetti Assessment Tool [29]. A total of 22 patients (11 allocated to the experimental and 11 allocated to the control group) would be needed to achieve a 97% and a 99% statistical power for the balance and gait subscales, respectively. Assuming 5% attrition, 24 patients will be recruited and allocated to one group or the other.

2.4. Intervention

The intervention will consist of 10 weeks and evaluations will be conducted before and after the intervention program. Both the evaluations and the intervention will be carried out in the facilities where participants live in order to avoid patient stress.

2.4.1. Experimental Group

The presented AAT program will comprise 20 sessions in 10 weeks. It will consist of carrying out different assisted therapeutic activities, explained below, wherein the dogs' role will be to improve the physical function and ability to move around the facility when both walking and climbing stairs. In addition to this AAT intervention, the participants will also continue carrying out their daily therapeutic activities.

Participants will receive the sessions twice per week and the therapies will always be conducted at the same time. The intervention will consist of using dog-human interaction

to walk, move through obstacle courses, climb stairs, or use a handrail. Sessions' settings will be in an environment known to the participants and with the presence of their reference professionals to facilitate their adherence and sense of security. Moreover, to have correct control of the participants, the sessions will be developed in groups of three participants. Nevertheless, if participants manifest phobia, aggression or behavioral alterations during the session that impede the correct development of the intervention and/or any reaction that may be considered dangerous for their health or the health of any of the members of the group (including the dog) they will be excluded from the experimental group.

The methodology of the sessions will be based on the facilitation of patients' movements through their dog and the natural benefits of human–dog interaction, so that, by having dogs as partners and collaborators in different activities, patients will achieve tasks that otherwise are more complicated or impossible for them. This is because people with ASD may feel pressured and not obey the instructions given by professionals. However, the presence of dogs may help to naturally conduct the desired activities and, therefore, to achieve the proposed objectives. Each session will last 30 min. The structure of each will follow the following order. First, a welcome period of 5 min, during which participants and technicians will introduce themselves with greetings between the patients and the dogs. Secondly, the central part of the sessions, with a duration of 20 min, will be focused on the specific objectives of the therapy. It will consist of the execution of diverse orders given by the professional, such as performing a circuit that includes active listening, going up and downstairs, ambulation, manipulation of objects and activities that involve interaction with their companions and with the dog. The sessions will end with a farewell period of 5 min in order to say goodbye to the dog, sometimes with food, sometimes only verbally, gesturally, and/or with petting. This approach has been followed by previous studies [30,31].

The professional team, with a multidisciplinary profile, will be composed of AAI experts (one physiotherapist and one social educator), two psychologists, one occupational therapist, two sport science professionals and another social educator. These professionals are researchers from the University or workers at collaborating entities. The collaboration of those professionals, who daily work with the participants of this study, is crucial to adequately design the intervention, engage participants, and make them feel secure during the whole intervention. The person in charge of the dog, acting as a technician, as well as the dog itself, will be the same in all sessions for each participant.

Regarding dogs and with the aim to reduce the possibility of suffering from stress during AAI sessions [32,33], they will be selected according to their temperament, adaptability, motivation, and willingness to engage in the sessions. The handler and the dog must be pet and owner, living together, and must have a mutual strong bond to ensure the adequate interpretation of dogs' body language and avoid any kind of stress or discomfort. However, this method, wherein the owner brings their dog to the therapy, could lead to transference or issues of competing priorities. While this is known, the preferred method is nonetheless handler/provider, due to the importance of identifying stress or discomfort in the dogs. In these cases, the handler will immediately stop the activity, have a break, and advance to another task. Dogs will follow a strict zoonosis procedure including behavioral, blood, urine, and feces analyses. Deworming, rabies, and tetraivalent vaccinations will be also required and fulfilled. AAT Office of the Rey Juan Carlos University will be ensured animal welfare through the intervention including physical health and avoiding animal fatigue or stress presence.

To ensure animals' wellbeing, dogs will be limited to 4 h/week and a rest of more than 15 min between sessions when there are two consecutive sessions. Furthermore, dog-training sessions must not be more frequent than 4/day and must last less than 10 min each one. The dog must not be hungry when training and must always have access to fresh water. All these statements have been followed in other studies [34,35] will be supervised by the head and academics of the Animal-Assisted Intervention Office of the University.

The dogs who will participate in the intervention are:

- Blues, a male Labrador Retriever, aged 5 years, sterilized and weighing 40 kg. Blues has experience in activities with people suffering from different disabilities and older adults with cognitive impairments.
- Josi, a female mix of Labrador Retriever, aged 11 years, sterilized and weighing 22 kg. Josi has experience with people with ASD, kids and people with drug addictions.

2.4.2. Usual Care Group

The control group of the study will continue with their daily life activities and the treatments carried out in their respective residences.

2.5. Outcomes and Measures

Participants from both groups will be evaluated at the beginning and the end of the study, within 7 days before and after the intervention starts and ends, respectively. As can be seen in Figure 1, there are three relevant times regarding evaluations: T1 (before the study begins), T2 (while the study is being doing), and T3 (once all sessions have been conducted). All variables will be evaluated twice (before and after the intervention), with the exception of the communication with the dog, which is evaluated three times during the sessions (in the first one, in the 11th and in the last one).

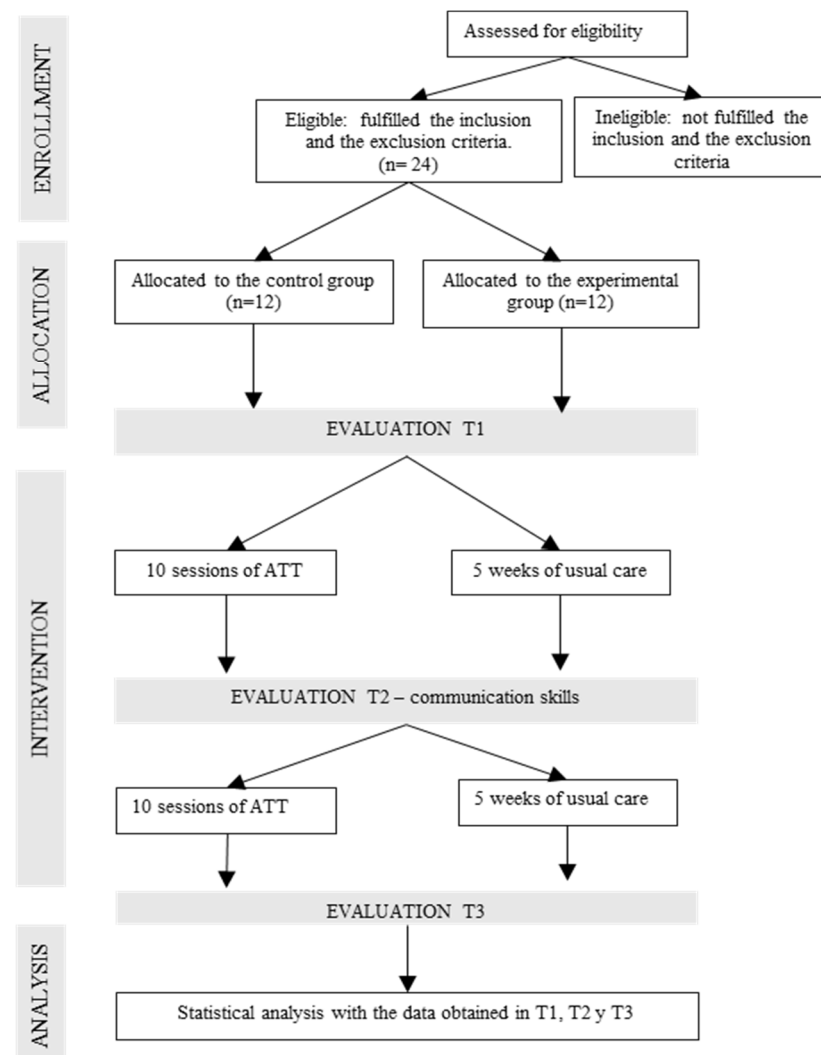


Figure 1. Protocol timeline implemented in the study.

The control group will only participate in the pre- and post-intervention evaluations, so there will be no data about communication with the dog for this group. The professionals

who usually are in contact with the participants in each association will be in charge of carrying out the assessment tests. As can be seen in Figure 1, apart from the pre- and post-intervention evaluations (which include the assessment of communication skills) there will be an intermediate evaluation of communication skills conducted during the sessions.

First, the sociodemographic variables will be collected including age, sex, between others. Besides, anthropometric measurements (height, weight, and length of segments used for the appropriate kinematic analyses with Kinovea Software), and relevant information concerning the disability and diagnosis of each participant will be stored.

2.5.1. Walking Performance

The evaluation of the walking ability over 6 and 10 m will be carried out in a straight corridor, measuring the time spent. Participants will perform this task at their natural self-selected pace. By using a two-distance test of 6 m and 10 m, in a corridor known to the participants, changes in the length of the steps, changes in cadence, and changes in the duration of the phases of the gait cycle will be evaluated. It will be performed at patients' preferred speed and in a straight line, on a smooth, non-slippery surface. To carry out this test, three marks will be placed on the ground, the starting mark, another mark at 6 m, and another mark at 10 m. This will allow the extraction of variables for the 6-m and 10-m tests. These walking tests are widely used, although the distance utilized in the literature is variable. It has been observed that a greater distance could increase the reliability of the test [36]. The 6-m test has been previously used in young adults with ASD, so obtaining data at this distance will allow comparison with that previous study [37]. The test will be recorded on video to obtain kinematic variables through the "Kinovea" software, which has shown good reliability in previous studies to obtain kinematic variables [38,39].

2.5.2. Balance and Risk of Falls

Participants' balance and risk of falls will be assessed using the Tinetti assessment tool [40]. The scale includes a balance test and a walking test. The minimum score that could be obtained is zero points and the maximum walking score could be 12 points, whereas the maximum score for the balance component could be 16 points. So that, the total score of the scale ranges from 0 to 28 points, with scorings equal to or lower than 25 indicate the existence of a risk of falling (higher scores mean a lower risk of falls). The Tinetti scale [40] has been formerly employed to assess balance and the risk of falls in people with intellectual disabilities [41,42].

2.5.3. Communication Abilities

During the first, intermediate, and last session in the dogs' presence, the communication skills of the experimental group will be assessed using an adapted version of the comprehensive and expressive language scale [43] to assess interaction and communication with dogs and other people. This scale was designed by a group of experts, including researchers from different disciplines, therapists, and educators with a significant experience with people with ASD. This scale will be completed by the staff according to the frequency of the occurrence of relevant behaviors, such as staring at the dog, fixing the attention to the dog, interacting with the dog (feeding, petting, grooming . . .), speaking with other people, naming objects or people, expressing feelings, or asking questions. This scale consists of 38 items scored 2 (yes, always), 1 (sometimes) or 0 (no, never) (Table 3). The minimum score that could be reached is 0 and the maximum score 76. Higher score scores mean better communication skills. The items are shown in Table 3. This scale will be administered during the first, intermediate and final sessions, and only in the experimental group, as the control group will not have contact with the dog.

Table 3. Items observed to evaluate the patients' communication and interaction during the sessions.

Items to Observe		
The patient		
Non-verbal communication		Verbal communication
1. Stares directly at the dog	12. Activities attract his/her attention	1. Talks to people,
2. Briefly looks at the dog	13. Shows rejection towards the dog	2. Talks to the dog
3. Focuses on the dog steadily	14. Touches the dog	3. Names the dog,
4. Focuses on the dog intermittently	15. Feeds the dog	4. Names the people,
5. Focuses on someone else who is with the dog	16. Plays with the dog	5. Names session's objects
6. Tries to direct attention to the dog	17. Brushes the dog	6. Names session's activities
7. Draws the attention of someone or the dog	18. Touches people when the dog is away	7. Expresses or show joy
8. Looks only at the dog,	19. Touches people when the dog is present	8. Expresses or show sadness
9. Looks only at the person	20. Interacts voluntarily with the dog	9. Expresses or show fear
10. Looks at the person and the dog	21. Uses the dog to communicate with people	10. Expresses or shows disgust
11. Objects attract his/her attention	22. Uses people to communicate with the dog	11. Expresses or shows surprise,
		12. Draws someone's or dog's attention
		13. Requests what they want,
		14. Goes to someone to ask for it
		15. Asks questions about the dog,
		16. Asks questions about people
		17. Answers simple questions

A reduced version of this scale (omitting the items related to the dog) will be administered without the presence of the dog and during the pre- and post-intervention assessments. This scale will consist of 14 items and both the control, and the experimental groups will be assessed in order to enable between-group comparisons. The minimum scoring of this 14-item scale is 0 and the maximum could be 28. Higher scores mean better communication and interaction. Psychometric properties will be extracted of this adapted version.

2.5.4. Ability to Climb and Descend Stairs

Patients will be evaluated through the Climbing and Descending Stairs Test (10 steps). Climbing and descending stairs are daily activities that require coordination and good physical function and that have been used by different previous studies in people with intellectual disabilities [44,45], in addition to being validated also in other pathologies [46]. The test will consist of going up and down a flight of stairs at the preferred speed, allowing the use of the handrail if the participant so wishes. The test will be recorded on video to obtain kinematic variables through the Kinovea software, which has shown good reliability in previous studies to obtain kinematic variables [38,39].

2.6. Statistical Analyses

First, the Kolmogorov–Smirnov and Shapiro–Wilk tests will be used to determine whether parametric or non-parametric statistical analyses should be applied. Descriptive results will be presented as mean and SD or median (range) according to the results of the normality tests. To evaluate the effects of the program, a repeated-measures ANOVA will be used. In this ANOVA, two groups (experimental or control) and two/three-time moments (pre, intermediate, and post) will be analyzed. Additionally, a Bonferroni adjustment will be made for this analysis. Although we plan to follow the mentioned statistical process, the final enrollment and completion will determine the appropriate test to performed.

Statistical analysis will be performed using SPSS statistical software (version 26.0; SPSS, Inc., Chicago, IL, USA) and the chosen significance level will be 0.05. All data will be analyzed and manipulated only by researchers.

3. Discussion

The current study aims to improve the daily living of institutionalized adults with ASD through a dog-assisted therapy focused on the enhancement of physical function and the ability to move around corridors and stairs. The growth of scientific knowledge about ASD in terms of diagnosis and therapies, as well as the increase in life expectancy of people with this disorder, has contributed to the increase in the prevalence and incidence of this group in recent decades [47–49]. This progressive increase of ASD populations is forcing the scientific, social, and health community to evaluate and optimize ASD patients' well-being together with increasing their quality of life [47–49].

Despite not having found scientific literature that could relate AAT with physical function in people with ASD, according to some studies, AAT with dogs could be a feasible complementary strategy to be included as part of the rehabilitation process experienced by people with physical disabilities, especially at the level of balance and eye–hand coordination [50]. However, the results obtained in this study, performed by Crespo et al. (2020), did not include the autistic population, and so needs to be confirmed by larger controlled clinical trials.

In this sense, the present study may represent a solid research plan to test the effectiveness of AATs in adults with ASD, in order to reduce the risk of falls through activities and circuits that involve walking and climbing or descending stairs, along with the known benefits of human–animal interaction, such as motivation, connection, calming, or stress-relieving [51,52]. Moreover, to our knowledge, this will be the first controlled trial to explore the efficacy of dog-assisted therapy on the gait of adults with ASD that may have walking disturbances due to potential physical and intellectual disturbances. Given the demonstrated importance of good psychomotor maintenance in achieving autonomy in ADL and quality of life, it is convenient to propose treatments that favor the development of these capacities, especially in people with neurodevelopmental disorders. AAI may be an adequate alternative to improve social interaction and communication skills since the animal acts as a social facilitator and a powerful motivator to carry out activities [15,53,54], directing this technique towards psychomotor and social objectives may be a quick and effective method for enhancing the autonomy of users with ASD and improving their quality of life.

However, after conducting this study, it will be still necessary to expand the field of research with further studies, on behalf of some of the limitations of the present study. First, regarding the methodological limitations, the current study will include neither randomized nor double-blind processes, which might influence interpretations of the results. In addition, the research will be focused only on the benefits deriving from the presence of the animal, without delving into its characteristics. Second, the uncertain health conditions in Spain due to COVID-19 may change during the study, which could modify patients' behavior or intervention procedures. Furthermore, the use of a face mask may continue to be mandatory, which may affect the comfort and the communication between patients and between the patient and the staff. Moreover, due to the pandemic circumstances, this therapeutic trial has already delayed.

In spite of these limitations, the results of this study will be useful to explore a comprehensive strategy that would help patients with ASD to increase their interaction and communication skills, as well as to increase their physical function and reduce their fall risk. These potential improvements may be also accompanied by the creation of habits and affective bonds with the dog, their peers and the professionals, which may contribute to the prevention of sedentary lifestyles, isolation, and dependence, among others.

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Institutional Review Board Statement: The study will be conducted according to the guidelines of the Declaration of Helsinki and approved by the Ethics Committee of Rey Juan Carlos University (approval number: 1901202103121).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

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